

# Transderm-Nitro® nitroglycerin Transdermal Therapeutic System

BRIEF SUMMARY (FOR FULL PRESCRIBING  
INFORMATION, SEE PACKAGE INSERT)

## INDICATIONS AND USAGE

This drug product has been conditionally approved by the FDA for the prevention and treatment of angina pectoris due to coronary artery disease. The conditional approval reflects a determination that the drug may be marketed while further investigation of its effectiveness is undertaken. A final evaluation of the effectiveness of the product will be announced by the FDA.

## CONTRAINDICATIONS

Intolerance of organic nitrate drugs, marked anemia, increased intraocular pressure or increased intracranial pressure.

## WARNINGS

In patients with acute myocardial infarction or congestive heart failure, Transderm-Nitro system should be used under careful clinical and/or hemodynamic monitoring. In terminating treatment of anginal patients, both the dosage and frequency of application must be gradually reduced over a period of 4 to 6 weeks to prevent sudden withdrawal reactions, which are characteristic of all vasodilators in the nitroglycerin class. Transdermal nitroglycerin systems should be removed before attempting defibrillation or cardioversion because of the potential for altered electrical conductivity which may enhance the possibility of arcing, a phenomenon associated with the use of defibrillators.

## PRECAUTIONS

Symptoms of hypotension, such as faintness, weakness or dizziness, particularly orthostatic hypotension may be due to overdosage. When these symptoms occur, the dosage should be reduced or use of the product discontinued. Transderm-Nitro system is not intended for immediate relief of anginal attacks. For this purpose occasional use of the sublingual preparations may be necessary.

## ADVERSE REACTIONS

Transient headaches are the most common side effect, especially when higher doses of the drug are used. These headaches should be treated with mild analgesics while Transderm-Nitro therapy is continued. When such headaches are unresponsive to treatment, the nitroglycerin dosage should be reduced or use of the product discontinued.

Adverse reactions reported less frequently include hypotension, increased heart rate, faintness, flushing, dizziness, nausea and vomiting. These symptoms are attributable to the known pharmacologic effects of nitroglycerin, but may be symptoms of overdosage. When they persist the dose should be reduced or use of the product discontinued. In some patients, dermatitis may occur.

## DOSAGE AND ADMINISTRATION

Therapy should be initiated with application of one Transderm-Nitro 5 system to the desired area of skin. Many patients prefer the chest; if hair is likely to interfere with system adhesion or removal, it can be clipped prior to placement of the system. Each system is designed to remain in place for 24 hours, and each successive application should be to a different skin area. Transderm-Nitro system should not be applied to the distal parts of the extremities.

The usual dosage is one Transderm-Nitro 5 system every 24 hours. Some patients, however, may require the Transderm-Nitro 10 system. If a single Transderm-Nitro 5 system fails to provide adequate clinical response, the patient should be instructed to remove it and apply either two Transderm-Nitro 5 systems or one Transderm-Nitro 10 system. More systems may be added as indicated by continued careful monitoring of clinical response. The Transderm-Nitro 2.5 system is useful principally for decreasing the dosage gradually, though it may provide adequate therapy for some patients when used alone.

The optimal dosage should be selected based upon the clinical response, side effects, and the effects of therapy upon blood pressure. The greatest attainable decrease in resting blood pressure that is not associated with clinical symptoms of hypotension especially during orthostasis indicates the optimal dosage. To decrease adverse reactions, the size and/or number of systems should be tailored to the individual patient's needs.

Do not store above 86°F (30°C).

## PATIENT INSTRUCTIONS FOR APPLICATIONS

A patient leaflet is supplied with the systems.

## HOW SUPPLIED

Transderm-Nitro System Rated Release in vivo	Total Nitroglycerin in System	System Size	Carton Size
2.5 mg/24 hr	12.5 mg	5 cm <sup>2</sup>	30 Systems (NDC 0083-2025-26) *100 Systems (NDC 0083-2025-30)
5 mg/24 hr	25 mg	10 cm <sup>2</sup>	30 Systems (NDC 0083-2105-26) *100 Systems (NDC 0083-2105-30)
10 mg/24 hr	50 mg	20 cm <sup>2</sup>	30 Systems (NDC 0083-2110-26) *100 Systems (NDC 0083-2110-30)
15 mg/24 hr	75 mg	30 cm <sup>2</sup>	30 Systems (NDC 0083-2115-26) *100 Systems (NDC 0083-2115-30)

\*Hospital Pack 100's

C85-35 (Rev. 11/85)

## Dist. by:

CIBA Pharmaceutical Company  
Division of CIBA-GEIGY Corporation  
Summit, New Jersey 07901

All transdermal nitroglycerin products are being marketed pending final evaluation of effectiveness by the FDA.

# In Memoriam

## California Medical Association

BARNES, JAMES P., Walnut Grove. Died May 21, 1987, aged 73. Graduate of University of Arkansas College of Medicine, Little Rock, 1940. Licensed in California in 1946. Dr Barnes was a member of the Sacramento-El Dorado Medical Society.

CARDEY, NORMAN L., Died Apr 17, 1987, aged 77. Graduate of Loma Linda University School of Medicine, 1934. Licensed in California in 1946. Dr Cardey was a member of the Los Angeles County Medical Association.

CARMACK, JAMES C. Died Apr 12, 1987, aged 90. Graduate of University of Texas, 1930. Licensed in California in 1931. Dr Carmack was a member of the San Bernardino County Medical Society.

CERV, ERNEST A. Died May 1987, aged 74. Graduate of University of Nebraska College of Medicine, Omaha, 1940. Licensed in California in 1945. Dr Cerv was a member of the Los Angeles County Medical Association.

CHATTERJEE, ALO, Merced. Died Apr 26, 1987, aged 43. Graduate of University of Calcutta, 1967. Licensed in California in 1975. Dr Chatterjee was a member of the Merced-Mari-  
posa Medical Society.

CHATTERJEE, CHITTA R., Merced. Died Apr 26, 1987, aged 51. Graduate of University of Calcutta, 1959. Licensed in California in 1975. Dr Chatterjee was a member of the Merced-Mari-  
posa Medical Society.

COY, L. PIERCE, San Mateo. Died May 30, 1987, aged 71. Graduate of Vanderbilt University School of Medicine, Nashville, Tenn, 1943. Licensed in California in 1946. Dr Coy was a member of the San Mateo County Medical Society.

CRAY, G. CAMERON, Palo Alto. Died Apr 27, 1987, aged 64. Graduate of State University of New York Downstate Medical Center, Brooklyn, 1951. Licensed in California in 1952. Dr Cray was a member of the Santa Clara County Medical Society.

ENGSTROM, ROBERT E. Died Apr 9, 1987, aged 57. Graduate of University of California, Irvine, 1962. Dr Engstrom was a member of the Los Angeles County Medical Association.

FRANKLIN, ROLAND G., Murrieta. Died Apr 5, 1987, aged 72. Graduate of University of Southern California School of Medicine, Los Angeles, 1941. Licensed in California in 1941. Dr Franklin was a member of the Riverside County Medical Association.

GARDINER, FREDERICK S. Died Feb 10, 1987, aged 73. Graduate of McGill University, Montreal, 1939. Licensed in California in 1947. Dr Gardiner was a member of the San Diego County Medical Society.

GUCKER, THOMAS, III. Died Mar 31, 1987, aged 71. Graduate of University of Pennsylvania School of Medicine, Philadelphia, 1941. Licensed in California in 1958. Dr Gucker was a member of the Los Angeles County Medical Association.

JESSUP, ROBERT BRUCE, Palo Alto. Died June 2, 1987, aged 67. Graduate of Stanford University School of Medicine, 1949. Licensed in California in 1949. Dr Jessup was a member of the Santa Clara County Medical Society.

KEARNEY, SANBORN G. Died Apr 5, 1987, aged 78. Graduate of University of California, 1935. Licensed in California in 1935. Dr Kearney was a member of the Kern County Medical Society.

KOENIGSBERGER, ERNST. Died Apr 22, 1987, aged 92. Graduate of University of Leipzig, 1922. Licensed in California in 1942. Dr Koenigsberger was a member of the Alameda-Contra Costa Medical Association.

LOIGNON, HENRI P., Port Hueneme. Died May 22, 1987, aged 58. Graduate of University of California, Irvine. Dr Loignon was a member of the Ventura County Medical Society.

LOPES, JOHN D., Mountain View. Died May 23, 1987, aged 64. Graduate of Jefferson Medical College, Philadelphia, 1950. Licensed in California in 1951. Dr Lopes was a member of the Santa Clara County Medical Society.

LUTZ, MICHAEL D. Died Mar 1987, aged 47. Graduate of University of North Carolina, Chapel Hill, 1968. Licensed in California in 1973. Dr Lutz was a member of the San Diego County Medical Society.

MCCREA, FRANCIS R. Died Feb 27, 1987, aged 95. Graduate of Stanford University, 1925. Licensed in California in 1925. Dr McCrea was a member of the Los Angeles County Medical Association.

MCGUIRE, FRANK A. Died Mar 3, 1987, aged 87. Graduate of University of Manitoba, Winnipeg, 1924. Dr McGuire was a member of the San Joaquin County Medical Society.

## New Mexico Medical Society

ALHADEFF, NORMAN L., Albuquerque. Died Jun 11, 1987, aged 38. Graduate of Tufts University School of Medicine, Boston, 1979. Licensed in New Mexico in 1986. Dr Alhadeff was a member of the Greater Albuquerque Medical Association.

BIVENS, MELVIN D., Albuquerque. Died Jun 3, 1987, aged 69. Graduate of University of Colorado School of Medicine, Denver, 1946. Licensed in New Mexico in 1953. Dr Bivens was a member of the Greater Albuquerque Medical Association.

MIX, NANCY J., Albuquerque. Died Jun 11, 1987, aged 37. Graduate of Boston University School of Medicine, 1974. Licensed in New Mexico in 1986. Dr Mix was a member of the Greater Albuquerque Medical Association.

## Utah State Medical Association

BUDGE, OLIVER W., Logan. Died May 19, 1987, aged 84. Graduate of Northwestern University Medical School, Chicago. Dr Budge was a member of the Cache Valley Medical Society.